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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/067,792	02/08/2002	Alison Joy Hodgkinson	P64057US1	3945

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EXAMINER	
SZPERKA, MICHAEL EDWARD	

ART UNIT	PAPER NUMBER
1644	

DATE MAILED: 05/23/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/067,792	HODGKINSON ET AL.	
	Examiner	Art Unit	
	Michael Szperka	1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on *21 March 2005*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *47-80* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *47-80* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. Applicant's reply filed on March 21, 2005 is acknowledged.

Claims 47-80 have been amended.

Claims 47- 80 are pending and under consideration in the instant application.

Applicant is thanked for updating the first line of the specification in the reply filed on March 21, 2005. Applicant is reminded to update the status of any applications that may have changed their status subsequent to the filing of their amendment to the specification.

2. Applicant's submission of the declaration of Dr. Colin Prosser under C.F.R. 1.132, received April 21, 2005 is acknowledged. This declaration provides data to indicate that the methods of application 10/067,792 yield a product that has a greater concentration of IgA than what is taught in the prior art. This declaration is not persuasive in overcoming the art rejections of record for the reasons set forth below and because concentrations of IgA are not currently recited in the claims.

Prior Grounds of Rejection

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. Claims 47-65 and 69-80 stand rejected under 35 U.S.C. 102(b) as being anticipated by Wilson et al. (Immunology, 1972, 23:313-320, see entire document, of record) as evidenced by Janeway et al. (Immunobiology, 3rd edition, 1997, pages 13:21 to 13:34, see entire document) and as evidenced by Cooper et al. (Current Protocols in Immunology, 1995, pages 2.4.1 to. 2.4.9, see entire document).

Wilson et al. teach that intramammary vaccination of pregnant cows with the bacteria *E. coli* leads to a significant increase in the concentration of IgA in the milk of vaccinated animals that is maintained for at least 28 days (see entire document, particularly Table 2 on page 317). Also taught is that the milk from vaccinated cows can then be ingested by newborn animals to prevent enteric infections (see particularly the second paragraph of page 319). The specification indicates on page 14, lines 32-36 that milk *per se* can be used as food or nutritional supplement, and as such the milk produced by Wilson et al. meets this limitation.

Applicant was reminded that the patentability of a product does not depend on its method of production. See MPEP 2113. The examiner indicated that is not known how

Applicant's process produces a product that is materially different from the one produced by Wilson et al. Therefore, limitations based upon the timing and routes of antigen administration, as well as the addition of adjuvants and antibiotics, were not considered to lend patentable weight to Applicant's claimed invention.

The declaration of Dr. Colin Prosser under 37 CFR 1.132 filed April 21, 2005 is insufficient to overcome the rejection of claims based upon the teachings of Wilson et al. as set forth in the last Office action. This declaration provides evidence that the method of immunization disclosed by applicant results in a high absolute concentration of IgA in milk, supporting Applicant's argument in the second full paragraph on page 9 of the reply received March 21, 2005, that Applicant's milk has more IgA than the milk disclosed by Wilson et al. However, limitations concerning the absolute concentration of IgA in milk are not recited in the current claims. It should be noted that data from the three immunization site experiments disclosed by Dr Prosser must be compared with the prior art since experiments using fewer immunization sites were not performed in parallel. Since the instant claims do not recite concentrations of IgA, the data provided by the declaration of Dr Prosser is not sufficient to overcome the rejection of record.

Applicant's arguments filed on pages 8-9 of the response filed on March 21, 2005 have been fully considered but they are not persuasive. Applicant has argued that the teachings of Wilson do not meet the limitations of the current claims in that Wilson does not teach a) a titer that is about 3 to 18 fold higher than conducting step (a) alone, b) all of the immunization routes and steps of the current claims, c) that the antibodies

produced by Wilson are antigen-specific, and d) that Applicant can achieve IgA levels as high as 0.75 g/l while Wilson discloses 0.16 g/l at best.

Applicant's argument d) is not relevant since antibody concentrations are not limitations found in the current claims. While it is true that Wilson et al. do not test their antibodies for antigen specificity, the well-known reason why vaccinations work is that they provoke an antigen specific response that protects the host from infection as taught by Janeway et al. (see entire document). As such, the antibodies produced by Wilson et al. inherently show specificity for *E. coli*, the immunizing antigen. Applicant is correct that Wilson et al. only perform intramammary immunization. However, part (a) of claims 47 and 80 consist of a single immunizing step. The vaccination protocol used by Wilson et al. gives multiple intramammary vaccinations on different days (see particularly the Materials and Methods subsection, Vaccination on page 314). It is also well known in the art that repeated exposure to antigen leads to an increase in the titer and affinity of antibody responses, with titer increases between 3 and 18 fold occurring routinely as evidenced by Cooper et al. (see entire document, particularly the fourth paragraph on page 2.4.1, the paragraph that spans page 2.4.6 and 2.4.7, Figure 2.4.2 wherein an increase in antibody concentration within Applicant's recited range is demonstrated, and the paragraph that spans pages 2.4.8 and 2.4.9). As such, since Wilson et al. gave repeated intramammary vaccinations, in essence repeating step (a), the antibody titer obtained by Wilson et al. is between 3 and 18 fold higher than what it would have been if Wilson et al. had performed only one intramammary vaccination. It should also be

noted that Wilson et al. obtained both milk and colostrum samples (see particularly the Materials and Methods subsection, Whey on page 314).

Again, Applicant is reminded that the structure of the product being claimed must be shown to differ from that of the prior art, even if the method used to produce that product is not found in the prior art. See MPEP 2113.

Therefore, the prior art anticipates the claimed invention.

5. The rejections made based upon the teachings of Sheldrake et al. and Takahashi et al. have been removed due to Applicant's amendment to the claims which introduce the new limitation of a titer of 3 to 18 fold greater than what would have been obtained by immunization step (a) alone. While Sheldrake et al. teach an immunization protocol that utilizes both intramammary and intraperitoneal vaccination, the repeated vaccination of either of these sites is not taught. Similarly, Takahashi does not teach a repetition of immunization steps. Therefore, the rejections have been withdrawn.

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

7. Claims 47 and 65-67 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Wilson et al. (Immunology, 1972, 23:313-320, see entire document, of record) in view of Baley et al. (Pediatrics, 1986, 78:225-232, see entire document, of record), for the reasons set forth in paragraph 8 of the office action mailed October 21, 2004.

The declaration of Dr. Colin Prosser under 37 CFR 1.132 filed April 21, 2005 is insufficient to overcome the rejection of claims based upon the teachings of Wilson et al. and Baley et al. as set forth in the last Office action because as has been previously indicated, the declaration indicates that use of Applicant's method produces milk with IgA concentrations greater than the concentrations taught in the prior art. However, the instant claims do not recite specific concentrations. As such, the declaration provides data to support arguments for limitations that are not present in the instant claims.

Applicant's arguments filed on pages 10 and 11 of the reply received March 21, 2005 have been fully considered but they are not persuasive. Applicant has argued that Wilson et al. does not meet all of the limitations of the instant claims, and that when the teachings of Baley et al. are added to those of Wilson et al., these combined teachings do not rectify the deficiencies in Wilson et al., specifically nether document teaches the newly recited range of between 3 and 18 fold over step (a) alone. As explained above, the examiner believes that Wilson et al. does support this new limitation, and as such its combination with the teachings of Baley et al. renders the instantly claimed product obvious over the prior art.

8. Claims 47 and 65-67 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Wilson et al. (Immunology, 1972, 23:313-320, see entire document, of record) in view of Cross et al. (J. Am. Vet. Med. Assoc. 1970, 157:1325-1330, see entire document, of record) for the reasons set forth in paragraph 9 of the office action mailed October 21, 2004.

The declaration of Dr. Colin Prosser under 37 CFR 1.132 filed April 21, 2005 is insufficient to overcome the rejection of claims based upon the teachings of Wilson et al. and Cross et al. as set forth in the last Office action because as has been previously indicated, the declaration indicates that use of Applicant's method produces milk with IgA concentrations greater than the concentrations taught in the prior art. However, the instant claims do not recite specific concentrations. As such, the declaration provides data to support arguments for limitations that are not present in the instant claims.

Applicant's arguments filed on pages 10 and 11 of the reply received March 21, 2005 have been fully considered but they are not persuasive. Applicant has argued that Wilson et al. does not meet all of the limitations of the instant claims, and that when the teachings of Cross et al. are added to those of Wilson et al., these combined teachings do not rectify the deficiencies in Wilson et al., specifically nether document teaches the newly recited range of between 3 and 18 fold over step (a) alone. As explained above, the examiner believes that Wilson et al. does support this new limitation, and as such its combination with the teachings of Cross et al. renders the instantly claimed product obvious over the prior art.

Double Patenting

9. The rejection of claims 47-80 as being unpatentable over claims 47-80 of copending Application No. 10/067,870 has been withdrawn in light of the terminal disclaimer filed by Applicant on March 21, 2005 which was accepted on April 15, 2005.

New Grounds of Rejection

10. The following are new grounds of rejection necessitated by Applicant's amendments filed on March 21, 2005.

Claim Rejections - 35 USC § 112

11. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

12. Claims 47-80 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claims contain subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention. This is a new matter rejection.

Applicant has amended the base claims to recite a titer that is "between 3 and 18 fold greater...than step (a) alone." Applicant has indicated in the paragraph that spans pages 8 and 9 of the response dated March 21, 2005, that support for the amendment can be found throughout the specification, especially the examples. The examiner has looked in the specification for the recited range of "between 3 and 18 fold" and has failed to find support for this limitation. Applicant is required to either point out more specifically where support for this range occurs, or remove this limitation from the claims.

13. Claims 47-80 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the amelioration or treatment of a gastroenteric disease, does not reasonably provide enablement for the prevention, amelioration or treatment of any disease. The specification does not enable any person skilled in the

art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

Applicant has claimed a composition containing IgA that is intended to be used for the prevention, treatment and/or amelioration of a disease. No diseases are recited in the claims, but the specification indicates the use of the claimed compositions in the treatment of gastroenteric disorders and infections (see particularly pages 13 and 14 of the instant specification). However, such conditions are not defined as limiting the scope of the diseases that can be treated with the claimed compositions. No examples are provided in the specification demonstrating that the administration of the claimed compositions was effective in preventing, ameliorating or treating any disease, gastroenteric or otherwise.

Many diseases do not involve the gastrointestinal tract. An example of such a disease is Parkinson's Disease. The Merck Manual teaches that the etiology of this disease is diverse, but gastrointestinal infection is not indicated as a possible trigger of the disease (The Merck Manual-second home edition, Parkinson's disease in chapter 61, pages 1-6, see entire document particularly the paragraph that begins with "Parkinsonism..." on page 1). Further, treatment with antibodies is not an art-accepted therapeutic method for the management of this disease that has no cure (see particularly the treatment section on pages 3-5). As such, there appears to be no evidence either in the art or in Applicant's specification that Applicant's claimed compositions would have any therapeutic benefit in treating a disease such as Parkinson's Disease. Further, prevention of a disease requires that administration of

Applicant's claimed compositions leads to a 100% effective prophylactic treatment at all times and in all cases. Such levels of efficacy are only rarely obtained in any treatment regimen. Therefore, since the specification does not provide working examples concerning the prevention or treatment of any disease, and the art indicates that not all diseases are amenable to treatment with antibodies and since prevention requires Applicant's compositions to be 100% effective at all times and in all circumstances, it would not be possible for a skilled artisan to use the compositions claimed by Applicant for preventing any disease or for ameliorating or treating non-gastroenteric diseases without first conducting additional research.

14. No claims are allowable.

15. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

16. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Szperka whose telephone number is 571-272-2934. The examiner can normally be reached on M-F 9-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on 571-272-0841. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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